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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,649	03/30/2001	Edward Soh Smith	RPA1006	8561
22829	7590	05/19/2004	EXAMINER	
ROCHE MOLECULAR SYSTEMS INC PATENT LAW DEPARTMENT 1145 ATLANTIC AVENUE ALAMEDA, CA 94501			GOLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

**Advisory Action****Application No.**

09/823,649

**Applicant(s)**

SMITH ET AL.

**Examiner**

Jeanine A Goldberg

**Art Unit**

1634

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 1-4,8-16,20-32,36-44 and 48-68.Claim(s) withdrawn from consideration: NONE.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

J. Goldberg

GARY BENZION, PH.D.

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600 of Paper No. 504

5/17/04

Continuation of 5. does NOT place the application in condition for allowance because: The arguments directed to the 112/1st Enablement rejection have been thoroughly considered, but deemed not persuasive. The declaration filed by Dr. David H. Gelfand is filed for the first time after final. The same issues were previously rejected in the first action, therefore, the declaration does not appear to be timely. Furthermore, response cites section of the declaration which provides numerous papers which have not been submitted for consideration. The examiner has not considered these references since they have not been provided.

The response argues that the skilled artisan would not synthesize and test 4 billion enzymes containing each of the species of motif as implied by the Office Action, but rather, the skilled artisan would identify polymerases comprising the motif by SEQ ID NO: 1. This argument has been thoroughly reviewed, but is not found persuasive because once the motif was identified, there would be about 4 billion enzymes encompassed by the motif which would need to be evaluated. Since the motif is very broad and encompasses such a large number of polymerases, it would be unpredictable which of these sequences would function as polymerases.

With respect to the 102(b) and 102(e) the response argues that the examiner fails to point out where in the experimental sections of the references the template for synthesis is an RNA molecule. This argument has been thoroughly reviewed, but is not found persuasive because as provided in the previous office action, and in the specification, reverse transcription requires an RNA template. The response also argues that the examiner has failed to show how the cited definition explicitly states that each of the activities listed in the definition is carried out by the same enzyme in the reaction mixture. This argument has been thoroughly reviewed, but is not found persuasive because the teachings of Gelfand, including the claims provide using the enzyme for DNA synthesis. DNA synthesis, as defined by the specification explicitly encompasses reverse transcription. The references specifically teach the enzymes are used in these DNA synthesis reactions. To assume or propose that the patent has not or did not intend to encompass each of these DNA synthesis methods, including reverse transcription, is contrary to the text of the patent.

With respect to the 103 rejection, Kawaskaki specifically teaches encompassing magnesium in the RTPCR reaction using a polymerase from any source. The response argues that it is unclear what is meant by the claims are not limited to the unexpected results over the prior art. This argument has been thoroughly reviewed, but is not found persuasive because as provided by 716.02(d), the MPEP states that the objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support. The instant claims are drawn to a much larger genus. The response argues that the unexpected results of a species may be supported by data showing unexpected results of a species under certain circumstances. The MPEP states that this is applicable if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the probative value thereof. The evidence of record does not appear to support that all the polymerases within the scope of the claim would be expected to function the same.